Notice of Allowability	Application No.	Applicant(s)	
	09/402,446	PRICE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *July 18, 2005*.

2. ☒ The allowed claim(s) is/are *23,25,26,31-39,59,60 and 64-73*.

3. ☒ The drawings filed on *07 October 1999* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

5-00

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Micheline Gravelle on July 18, 2005.

2. The application has been amended as follows:

Claims 1-22, 24, 27-30, 40-46,58, 61-63 and 74-80 are cancelled.

Claim 25 (currently amended) The ~~[A]~~ method according to claim 23 wherein the ant-Rh_OD immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 26 (currently amended): The ~~[A]~~ method according to claim 25 wherein the immune globulin preparation is an aqueous formulation.

Claim 31 (currently amended): The ~~[A]~~ method according to claim 23 wherein the non-ionic surface active agent is a sorbitan ester of a fatty acid.

Claim 32 (currently amended): The ~~[A]~~ method according to claim 31 wherein the non-ionic surface active agent is selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 33 (currently amended): The ~~[A]~~ method according to claim 23 wherein the surface active agent is a polyoxyethylene sorbitan ester of a fatty acid.

Claim 34 (currently amended): The ~~[A]~~ method according to claim 33 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

Claim 35 (currently amended): The ~~[A]~~ method according to claim 23 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate', polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and sorbitan trioleate.

Claim 36 (currently amended): The ~~[A]~~ method according to claim 23 wherein the concentration of the non-ionic surface active agent is about 0.01 weight percent to about 0.5 weight percent.

Claim 37 (currently amended): The ~~[A]~~ method according to claim 23 wherein the immune globulin preparation is a lyophilized preparation that is reconstituted in a physiologically compatible medium prior to administration to the animal.

Claim 38 (currently amended): The ~~[A]~~ method according to claim 23 wherein the immune globulin preparation comprises:

about 3-8% human anti-Rh_OD immune globulin with an lgG purity of greater than 95% and a monomeric protein content of greater than 94%;

sodium chloride at about 0.25% (w/v);

polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and

L-glycine at about 0.1M.

Claim 39 (currently amended): The ~~[A]~~ method according to claim 23 wherein the non-ionic surface agents is selected from the group consisting of glyceryl monooleate and a polyvinyl alcohol.

Claim 59 (currently amended): The ~~[A]~~ method according to claim 57 wherein the anti-Rh_OD immune globulin has an lgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 60 (currently amended): The ~~[A]~~ method according to claim 59 wherein the immune globulin preparation is an aqueous formulation.

Claim 64 (currently amended): The ~~[A]~~ method according to claim 57 wherein the concentration of the anti-RhoD immune globulin is about 2 weight percent to about 10 weight percent.

Claim 65 (currently amended): The ~~[A]~~ method according to claim 57 wherein the non-ionic surface active agent is a sorbitan ester of a fatty acid.

Claim 66 (currently amended): The ~~[A]~~ method according to claim 65 wherein the non-ionic surface active agent is selected from the group consisting of sorbitan monolaurate, sorbitan

monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 67 (currently amended): The [~~A~~] method according to claim 65 wherein the non-ionic surface active agent is a polyoxyethylene sorbitan ester of a fatty acid.

Claim 68 (currently amended): The [~~A~~] method according to claim 67 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan .monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

Claim 69 (currently amended): The [~~A~~] method according to claim 57 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate', polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, [~~and~~] polyoxyethylene (20). sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 70 (currently amended): The [~~A~~] method according to claim 57 wherein the concentration of the non-ionic surface active agent is about 0.01 weight percent to about 0.5 weight percent.

Claim 71 (currently amended): The ~~[A]~~ method according to claim 57 wherein the immune globulin preparation is a lyophilized preparation that is reconstituted in a physiologically compatible medium prior to administration to the animal.

Claim 72 (currently amended): The ~~[A]~~ method according to claim 57 wherein the immune globulin preparation comprises:

about 3-8% human anti-RhoD immune globulin with an lgG purity of greater than 95% and a monomeric protein content of greater than 94%,

sodium chloride at about 0.25% (w/v);

polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and

L-glycine at about 0.1M.

Claim 73 (currently amended): The ~~[A]~~ method according to claim 57 wherein the non-ionic surface agent is selected from the group consisting of glyceryl monooleate; and a polyvinyl alcohol.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments:

a) The rejection of claims 74 and 78-80 under 35 U.S.C. 102(b) as being anticipated by Friesen (CA 1,201,063); and

b) The rejection of claims 74-76 and 80 under 35 U.S.C. 102(b) as being anticipated by DeBurgh Bradley et al., (CA 1,303,533).

Allowable Subject Matter

4. Claims 23, 25-26, 31-39, 57, 59-60, 64-73 are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 20, 2005